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EXAMINER

LEVKOVICH, NATALIA A

ART UNIT	PAPER NUMBER
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1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/784,092	Applicant(s) GRUDZIEN ET AL.	
	Examiner NATALIA LEVKOVICH	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 21-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/20/2004, 10/11/2005 and 03/17/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Invention I (claims 1-20) made without traverse in the reply filed on 04/07/2008, is acknowledged. With respect to the Species I and II, previously identified within the Invention I as being patentably distinct, upon further consideration and in light of arguments presented by the Applicant,, the corresponding further restriction has been WITHDRAWN.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 12 recite a "gasket means having wells fluidically coupled to the wells in the plate and combining with the wells in the plate...". In light of the common meaning of the terms "combine" (that is, "put together so as to form a whole") and "couple (that is, "connect, link, or associate together in a pair or pairs"), this limitation is unclear. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board

of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation of the gasket wells being combined with the plate wells, and the claim also recites the gasket wells being fluidically coupled to the plate wells which is the narrower statement of the range/limitation.

Additionally, claims 1 and 12 do not set forth sufficient structural inter-relationships between the gasket and the substrate, since the recitation of the gasket wells being "coupled to" and "combining with the wells in the plate", in order to form reaction chambers "about the reaction surfaces on the substrate", does not clearly define whether or not the gasket is attached to the substrate. See also claim 13.

Claim 2 recites a pair of "opposed clamp members joinable to opposed sides of the joined plate, the gasket means and the substrate". It is unclear whether or not this means that the clamp members are pre-arranged to be opposed relative to each other prior to being joined to the opposed sides of the assembly.

In claim 3, the "recess" lacks antecedent basis. Is it the same as "one open ended aperture" of line 2?

Claim 11 provides for the use of the apparatus of claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 11 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 16 recites the step of “forming the clamp members with an open channel”. This is a passive limitation, because it merely names a result of some unspecified actions leading to the result. Thus, some essential method steps are omitted, such omission amounting to a gap between the steps. Therefore, the claim is incomplete. See MPEP § 2172.01. The same considerations apply to claim 19, with respect to forming a sloped surface.

With respect to claim 17, “abutting the clamp members in a foot print of a microtitre plate”, is unclear.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5 and 11-16 are rejected under 35 U.S.C. 102(b) as anticipated by Hudson et al. (US 5591646).

Hudson discloses a peptide screening apparatus comprising, as shown in Figures 1 and 2 a-b, planar substrate plate 5 with a plurality of reaction areas 6, block 12 with a plurality of openings 13, 14, 15 etc. [‘plate with wells’] and silicone rubber gasket 10 having an array of through holes 11 which are fluidically coupled to the openings of plate 12, the holes and the openings jointly forming reaction chambers “about the reaction surfaces of the substrate” (Col.9, lines 20 plus). Figure 5 also shows opposed C-shaped clamps 42, 43 having a central wall, legs and teeth shaped extending projections (not indexed) “releasably engagable “ with an open ended aperture / recess 45 formed in the plate by ridge 41.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 6-10 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hudson et al. in view of McGrath et al. (US 5192503), and further in view of Juncosa et al. (US 6225109).

With respect to claims 6-7, 9 and 17-18, Hudson does not teach forming an array of co-planar substrate-gasket-plate stacks joined by clamps such that the array would have a foot print of a micro-titer plate.

McGrath discloses, as shown in Figures 1- 7, a system of co-planar stacked slides arranged on a bottom tray 126, each stack being individually joined by clamps (Abstract; Col.10, lines 60 plus).

Juncosa discloses a co-planar array of assay devices comprising stacked slides (illustrated in Figures 13-14). "A plurality of synthesis devices can be positioned in a support base ['tray' – Ex.] in order to allow sampling in an automated manner. The synthesis devices can be provided in a 96 well microtiter format" (Abstract). It would have been within the ordinary skill of an artisan at the time the invention was made to have arranged the diagnostic devices of Hudson in a similar manner, that is, in a tray supported co-planar array having micro-titer plate format, in order to increase productivity of the diagnostic apparatus and to allow sample handling at a higher automation level.

Referring to claims 8 and 19, Figure 3 of McGrath shows the slide supporting tray with recessed areas 140 guiding the slides into the tray. Additionally, trays having

sloped areas are routinely used in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed a tray with sloped areas in the modified apparatus of Hudson, in order to facilitate handling of individual devices on the tray.

Regarding claims 10 and 20, Hudson teaches hot-melt polyethylene adhesives ['non-releasible adhesives'] used for fixing bead supports to the substrate. It would have been also within the ordinary skill of an artisan at the time the invention was made to have employed such adhesives for joining the planar components of the stack (including the plate and the gasket) in the modified apparatus of Hudson, in order to provide better sealing for the reaction chambers.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1, 12 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5-6, 26 and 30-31 of US 7063979. Although the conflicting claims are not identical, they are not patentably distinct from each other because many limitations of the instant claims are entirely within the scope of the listed above claims of US 7063979. The difference is clamps used for compressing and connecting the substrate-gasket-plate stacks. It would have been obvious to one having ordinary skill in the art to modify invention of claims 1, 5-6, 26 and 30-31 of US 7063979, to include clamps to provide better sealing and additional stability to the plate assembly and to have the capability to conduct more reactions simultaneously to diversify the tests which can be performed.

11. Claims 1-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14, 17-22, 24-26, 30-32, 36 and 40-42 of copending application 10/349347.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to array devices and method of their preparation, the devices comprising at least one stack of an assay substrate, a gasket with a plurality of apertures and a multi-well plate clamped together to form a

diagnostic device. Thus, all the elements of the invention recited in the instant claims 1-20, are fully encompassed by the above listed claims of 10/349347.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 and 15-16 of copending application 11/236979.

Although the conflicting claims are not identical, they are not patentably distinct from each other because many limitations of the instant claims are entirely within the scope of the listed above claims of the copending application. The difference is, clamps being used in the instant application for compressing and connecting the substrate-gasket-plate stacks, instead of latches, as claimed in the copending application. However, clamps and latches are well recognized in the art as equivalent means of attachment. It would have been obvious to one having ordinary skill in the art to modify invention of claims 1-8 and 15-16 of copending application 11/236979, to use clamps for fixing the stacks, since clamps, as well as latches, are simple, reliable and commercially available attachments means, selecting between the two would be a simple engineering choice.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 2 p.m.-10 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797